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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,081	09/12/2003	Benjamin J. Feldman	12008.32USD1	9809
23552	7590	09/16/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			NGUYEN, DONGHAI D	
			ART UNIT	PAPER NUMBER
			3729	
DATE MAILED: 09/16/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/662,081	Applicant(s) FELDMAN ET AL.	
	Examiner Donghai D. Nguyen	Art Unit 3729	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-5 and 7-27 is/are pending in the application.
- 4a) Of the above claim(s) 7-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 18-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Response to Amendment*

1. Applicants' amendment filed on June 23, 2005 has been considered and made of record.

### *Election/Restrictions*

2. Claims 7-17 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected **Species B**, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 23, 2005.

### *Double Patenting*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 3-5 and 18-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5, 7-9, 22-24, 26 and 29 of U.S. Patent No. 6,618,934 B1 to Feldman et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed by the instant application is fully claimed in the patent and is covered by the Patent as follows:

Regarding claim 1, 5, 23, 24 and 27, Feldman et al claim the method of making sensor comprising: applying a plurality of working electrodes on a substrate and a plurality of counter electrodes on the substrate (claim 3, lines 3-9); applying indicator electrodes on one of the substrates (claim 7, lines 2-3); overlaying the electrode with a second substrate (claim 3, step e); creating a sample chamber region between the substrate having the electrodes and the second substrate, the sample chamber region having a volume of no more than 1  $\mu$ L or .5  $\mu$ L (claim 3, lines 28-29 and claim 19, lines 7-8); and separating a plurality of, electrochemical sensors, each electrochemical sensor comprising at least one working electrode planar with at least one counter electrode, and at least one sample chamber region (claim 3, step f).

Regarding claims 3-4, 18-22 and 25-26, Feldman et al disclose the spacer layer (Claim 3 step e); an adhesive layer (claim 21); applying working and counter electrodes by printing or screen printing (claim 8, lines 3-6); and removing a portion of space before or after position it between the substrates (claims 4 and 5).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 18, 19 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,708,247 to McAleer et al in view of US Patent 5,387,329 to Foos et al.

Regarding claims 1, 23, 24, and 27, McAleer et al disclose a method of manufacturing test sensor the method comprising: applying a plurality of working electrodes (14'/14) on a substrate (10); applying a plurality of counter electrodes (16/15) on the substrate; overlaying the electrode with a second substrate (23); creating a sample chamber region (a region of 17) between the substrate having the electrodes and the second substrate (see, Fig. 1A); and separating a plurality of, electrochemical sensors, each electrochemical sensor comprising at least one working electrode planar with at least one counter electrode, and at least one sample chamber region (Col. 6, lines, 15-17). McAleer et al do not teach the forming of indicator electrodes on one of the substrate and the volume of the sample chamber region. Foos et al teach the forming of indicator electrodes (50) on the substrate (32) and the sample chamber region (62, see Foos' Fig. 3) having a volume of no more than 1  $\mu$ L (see Col. 27, lines, 14-20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify invention of McAleer et al by the teaching of forming the indicator electrodes on one substrate and the volume of the sample chamber region as taught and suggested by Foos et al

(see Foos, Col. 27, lines 11-13) in order to obtain a desired sensor structure for measuring and analyzing of blood sample, etc. (see Col. 27, lines 11-23).

Regarding claims 3, McAleer et al disclose the positioning a spacer layer (18) between the substrate having the electrodes and the second substrate.

Regarding claims 18 and 19, McAleer et al disclose the step of applying a plurality of working electrodes on a substrate by printing, screen printing or ink jet printing (See Col. 5, lines 53-67).

Regarding claims 21, 22, 25 and 26, McAleer et al and Foos et al. do not disclose the removing a portion of the spacer before or after the step of disposing the spacer on the first or second substrate. It would have been obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to remove a portion of spacer to form a sample chamber between the first and second substrates in the sequence order include the above discussion. Since Applicants have not disclosed that the particular portion of the spacer being removed in order of before or after the disposing the spacer on the first or second substrate would require for a particular purpose, or solve a stated problem, and it appears that the invention would perform equally well with the teaching of the prior art and references (see McAleer Col. 6, lines 15-17).

7. Claims 4-5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al in view of Foos et al as applied above, and further in view of US Patent 6,129,823 to Hughes et al.

Regarding claims 4 and 20, McAleer/Foos et al as applied and relied upon above do not teach an adhesive layer. Hughes et al teach the step of positioning an adhesive layer between the substrate having the electrodes and the second substrate is done before the step of creating a sample chamber region (30, see Fig. 1) for bonding layers together (Col. 6, lines 10-12). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify the invention of McAleer/Foos et al by applying the teaching of applying the adhesive layer between the substrates as taught by Hughes et al to form an integral chamber region by using adhesive for positioning and bonding.

The limitation of claims 5 and 20 are also satisfied as set forth above.

#### *Response to Arguments*

8. Applicant's arguments with respect to claims 1, 3-6 and 18-27 have been considered but are moot in view of the new ground(s) of rejection.

9. Regarding claim 5, the indication of allowability set forth in the previous action is withdrawn because Applicants have amended the claims 1 and 3-5 that alters and changes the scope of the claimed invention therefore the prosecution is reopened in view of the new ground of rejection above.

10. This application contains claims 7-17 drawn to an invention nonelected without traverse in Amendment filed on June 23, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

*Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art references cited for the teachings of method for making an electrochemical sensor or the like.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action: Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donghai D. Nguyen whose telephone number is (571)-272-4566. The examiner can normally be reached on Monday-Friday (9:00-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter D. Vo can be reached on (571)-272-4690. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3729

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DN  
September 8, 2005

  
**MINH TRINH**  
**PRIMARY EXAMINER**